



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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Mary-Ellen M. Devlin
BOEHRINGER INGELHEIM
PHARMACEUTICALS INC.
900 Ridgebury Rd., P.O. Box 368
Ridgefield CT 06877-0368

Re: Patent Term Extension
Application for
U.S. Patent No. 5,216,167, Reissue
Patent No. 37,035

Dear Ms. Devlin:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,216,167, Reissue Patent No. 37,035 for a period of 921 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: PRANDIN™ (repaglinide)
FDA Docket No. 98E-0616

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

REISSUE PATENT NO. : RE 37,035
ISSUED : January 30, 2001
REISSUE OF U.S. PATENT NO. : 5,216,167
ISSUED : June 1, 1993
INVENTORS : Wolfgang Grell et al.
PATENT OWNER : Dr. Karl Thomae GmbH
PRODUCT : PRANDIN™ (repaglinide)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,216,167, now U.S. Reissue Patent No. RE 37,035, based upon the regulatory review of the product PRANDIN™ (repaglinide) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

921 days

from September 5, 2006, the original expiration date of the reissue patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 8th day of February 2001.

Nicholas P. Godici

Nicholas P. Godici

Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office